

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION**

LIFENET, INC.

Plaintiff,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN
SERVICES,

U.S. DEPARTMENT OF LABOR,

U.S. DEPARTMENT OF THE TREASURY,

OFFICE OF PERSONNEL MANAGEMENT,

and the

CURRENT HEADS OF THOSE
AGENCIES IN THEIR OFFICIAL
CAPACITIES,

Defendants.

Case No. 6: 22-cv-00162-JDK

**PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT
AND MEMORANDUM IN SUPPORT THEREOF**

TABLE OF CONTENTS

INTRODUCTION	1
STATEMENT OF THE ISSUES.....	2
STATEMENT OF UNDISPUTED MATERIAL FACTS	3
I. The No Surprises Act.....	3
II. There Is <i>No</i> Relevant Difference Between the Statutory Provision Regarding <i>Non</i> -Air Ambulance IDRs (Section 300gg-111) and the Statutory Provision Regarding Air Ambulance IDRs (Section 300gg-112)	3
III. There Is <i>No</i> Relevant Difference Between the Implementing Regulation Regarding <i>Non</i> -Air Ambulance IDRs (45 C.F.R. § 149.510) and the Implementing Regulation Regarding Air Ambulance IDRs (45 C.F.R. § 149.520)	6
IV. The Departments Continue to Require the QPA Presumption in Air Ambulance IDRs	10
V. Undisputed Material Facts Relevant to Plaintiff’s Standing.....	11
ARGUMENT.....	12
I. The QPA Presumption Conflicts with the Statutory Text of the NSA	12
II. The QPA Presumption Should Be Set Aside Because the Departments Failed to Provide for Public Notice and Comment	14
A. There Is No Exception to Notice-and-Comment for Regulations Concerning Air Ambulance IDRs.....	14
B. There Was No “Good Cause” For Not Providing Notice and Comment .	14
III. The Departments’ Application of the QPA Presumption <i>Solely</i> In Air Ambulance IDRs, And <i>Not</i> In Other IDRs, Conflicts with the Statute and Is Arbitrary and Capricious	15
IV. LifeNet Has Standing.....	17
A. Article III Standing	17
B. LifeNet Has “Prudential” Standing.....	23
CONCLUSION.....	23

TABLE OF AUTHORITIES**Page(s)****Cases**

<i>Am. Petroleum Inst. v. Johnson</i> , 541 F. Supp. 2d 165 (D.D.C. 2008)	17
<i>Ass'n of Data Processing Serv. Organizations, Inc. v. Camp</i> , 397 U.S. 150 (1970)	21
<i>Christopher v. SmithKline Beecham Corp.</i> , 567 U.S. 142 (2012)	17
<i>Clinton v. City of New York</i> , 524 U.S. 417 (1998)	21
<i>Cranor v. 5 Star Nutrition, L.L.C.</i> , 998 F.3d 686 (5th Cir. 2021)	21, 22, 23
<i>Duarte v. City of Lewisville</i> , 759 F.3d 514 (5th Cir. 2014)	18
<i>Fox v. Clinton</i> , 684 F.3d 67 (D.C. Cir. 2012)	17
<i>Judulang v. Holder</i> , 565 U.S. 42 (2011)	17
<i>Lujan v. Defs. of Wildlife</i> , 504 U.S. 555 (1992)	18, 19
<i>Markle Interests, LLC v. U.S. Fish & Wildlife Serv.</i> , 40 F. Supp. 3d 744 (E.D. La. 2014)	17
<i>Match-E-Be-Nash-She-Wish Band of Pottawatomi Indians v. Patchak</i> , 567 U.S. 209 (2012)	23
<i>Meland v. Weber</i> , 2 F.4th 838 (9th Cir. 2021)	18
<i>Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.</i> , 463 U.S. 29 (1983)	17
<i>Owner-Operator Indep. Drivers Ass'n, Inc. v. Fed. Motor Carrier Safety Admin.</i> , 656 F.3d 580 (7th Cir. 2011)	18
<i>Robins v. Spokeo, Inc.</i> , 867 F.3d 1108 (9th Cir. 2017), <i>cert. denied</i> , 138 S. Ct. 931 (2018)	22, 23

<i>Smiley v. Citibank (S. Dakota), N.A.</i> , 517 U.S. 735 (1996).....	16
<i>Susan B. Anthony List v. Driehaus</i> , 573 U.S. 149 (2014).....	20
<i>Texas Med. Ass’n v. United States Dep’t of Health & Hum. Servs.</i> , No. 6:21-CV-425-JDK, 2022 WL 542879 (E.D. Tex. Feb. 23, 2022)	<i>passim</i>
<i>Texas v. EEOC</i> , 933 F.3d 433 (5th Cir. 2019)	19
<i>Venetian Casino Resort, L.L.C. v. EEOC</i> , 530 F.3d 925 (D.C. Cir. 2008)	17
Statutes	
5 U.S.C. § 553(b), (c).....	14
5 U.S.C. § 559.....	14
5 U.S.C. § 706(2)(A).....	15
26 U.S.C. §§ 9816(c) & 9817(b).....	3
29 U.S.C. §§ 1185e(c) & 1185f(b)	3
42 U.S.C. § 300gg-111	<i>passim</i>
Other Authorities	
26 C.F.R. § 54.9817-2T(b)(2).....	23
29 C.F.R. § 2590.717-2(b)(2)	23
45 C.F.R. Part 149.....	<i>passim</i>
Restatement (First) of Torts § 624 (1938)	23
Restatement (Second) of Torts §§ 623A-629 (1977).....	23

Plaintiff respectfully moves for summary judgment on Counts I and II of Plaintiff's Complaint, which are essentially the same as Counts I and II of the complaint filed by the plaintiffs in *Texas Med. Ass'n v. United States Dep't of Health & Hum. Servs.*, No. 6:21-CV-425-JDK, 2022 WL 542879, at *1 (E.D. Tex. Feb. 23, 2022) ("*TMA*").

INTRODUCTION

This case is about a single sentence in the implementing regulations of the No Surprises Act. This Court's *TMA* decision already vacated *an identical sentence*:

45 C.F.R. § 149.510(c)(4)(iii)(C) (bold language, <u><i>vacated</i></u> by the <i>TMA</i> Decision, applies to <i>non-air</i> ambulance IDRs)	45 C.F.R. § 149.520(b)(2) (bold language is <u><i>still being applied by the Defendants</i></u> to require the QPA Presumption in <i>air-ambulance</i> IDRs)
Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(1) through (5) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.	Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.

This single sentence should be vacated (again) for the reasons given in *TMA*: *first*, the QPA Presumption conflicts with the unambiguous provisions of the text of the No Surprises Act; *second*, the Defendants failed to provide the required notice-and-comment.

In addition, this sentence should also be vacated for another reason: enforcing the QPA Presumption against *solely* air ambulance providers would arbitrarily and irrationally discriminate against them, with no basis in the statutory text for that differential treatment.

Plaintiff LifeNet has standing to bring this challenge. LifeNet, like the individual doctor plaintiff in *TMA* (Dr. Adam Corley), does not itself submit claims to the IDR process. Instead, LifeNet is compensated by non-party Air Methods Corporation—just as Dr. Corley received an hourly salary from non-party Precision Emergency Physicians, PLLC. LifeNet, like Dr. Corley, nevertheless has standing because LifeNet is a regulated party, i.e., is the “object of” the relevant regulations. The QPA Presumption effects both a procedural injury-in-fact and an economic injury-in-fact on LifeNet, just as it did on Dr. Corley. Furthermore, a lower-than-appropriate IDR determination is itself an immediate intangible harm to LifeNet because it assigns a low dollar value to LifeNet’s services in a critically important market.

STATEMENT OF THE ISSUES

The first two issues presented are identical to those presented in the *TMA* plaintiffs’ motion for summary judgment:

1. Did the Departments act contrary to law and/or exceed their statutory authority when, without any basis in the statutory text, they [enacted the QPA Presumption] . . . ?
2. Did the Departments have good cause for issuing the [QPA Presumption] without providing notice and comment as required by the APA . . . ?

TMA, Plaintiffs’ Mot. Summary Judgment, ECF 25, at 3.

The other issues presented are:

3. Are the Departments acting arbitrarily and capriciously by continuing to apply the QPA Presumption solely in air ambulance IDRs, without any statutory or rational basis for discriminating in this way against air ambulance providers?
4. Does Plaintiff have standing?

STATEMENT OF UNDISPUTED MATERIAL FACTS

I. The No Surprises Act

The No Surprises Act (“NSA”) was enacted on December 27, 2020, as part of the Consolidated Appropriations Act of 2021 to address “surprise medical bills.” *TMA*, 2022 WL 542879, at *1 (citing Pub. L. No. 116-260, div. BB, tit. I, 134 Stat. 1182, 2758–2890 (2020)).

The NSA made parallel amendments to provisions of the Public Health Service (“PHS”) Act, which is enforced by the Department of Health and Human Services (“HHS”); the Employee Retirement Income Security Act (“ERISA”), which is enforced by the Department of Labor; and the Internal Revenue Code (“IRC”), which is enforced by the Department of the Treasury. These Departments, along with the Office of Personnel Management (which oversees health benefits plans offered by carriers under the Federal Employees Health Benefits Act), issued the implementing regulations challenged here, and are referred to collectively as “the Departments.”

The relevant statutory and regulatory provisions at issue generally appear in triplicate. The NSA’s IDR provisions are codified at 42 U.S.C. §§ 300gg-111(c) & 300gg-112(b) (PHS Act), 29 U.S.C. §§ 1185e(c) & 1185f(b) (ERISA), and 26 U.S.C. §§ 9816(c) & 9817(b) (IRC). For ease of reference, this brief—like *TMA*—cites the PHS Act provisions and implementing regulations.

II. There Is *No* Relevant Difference Between the Statutory Provision Regarding *Non-Air Ambulance* IDRs (Section 300gg-111) and the Statutory Provision Regarding *Air Ambulance* IDRs (Section 300gg-112)

This Court in *TMA* considered Section 300gg-111 of the NSA, which sets forth the procedures to be followed in *non-air-ambulance* IDRs. *TMA*, 2022 WL 542879, at *1-*3 (describing the relevant provisions of 42 U.S.C. § 300gg-111). This Section also defines the statutory term “qualifying payment amount” (QPA) and provides instructions for calculating the QPA. “The QPA is generally ‘the median of the contracted rates recognized by the plan or issuer ... under such plans or coverage, respectively, on January 31, 2019, for the same or a similar item

or service that is provided by a provider in the same or similar specialty and provided in the geographic region in which the item[s] or service is furnished,’ with annual increases based on the consumer price index.” *TMA*, 2022 WL 542879, at *2 (quoting 42 U.S.C. § 300gg-111(a)(3)(E)(i)(I)-(II)).

The very next provision of the statute—Section 300gg-112—sets forth the procedures to be followed in *air ambulance* IDRs. *See* 42 U.S.C. § 300gg-112(b)(1)(A) (“In general—With respect to air ambulance services furnished . . . by a nonparticipating provider”). Section 300gg-112 was not cited in the *TMA* decision, likely because no air ambulance provider was a plaintiff in *TMA*.

There is *no* relevant difference between Section 300gg-112 and Section 300gg-111 for purposes of the QPA Presumption challenged by the *TMA* plaintiffs and by Plaintiff LifeNet here. Section 300gg-112, like Section 300gg-111, provides that an air ambulance IDR is a “baseball-style” arbitration in which the IDR entity chooses between the two competing offers submitted by the provider and by the health plan or insurer. The relevant statutory text is exactly the same. *See* 42 U.S.C. § 300gg-112(b)(5)(A)(i) (“the certified IDR entity shall--(i) taking into account the considerations specified in subparagraph (C), select one of the offers submitted under subparagraph (B) to be the amount of payment for such services”).

Section 300gg-112 adopts by reference the definition of the QPA, and the calculation method for the QPA, that are set forth in Section 300gg-111(a)(3). *See* 42 U.S.C. § 300gg-112(b)(5)(C)(i) (using QPA “as defined in section 300gg-111(a)(3)”).

Most important, the relevant statutory text—regarding what weight to give to the QPA—is identical in both sections. *Compare* 42 U.S.C. § 300gg-112(b)(5)(C)(i) (“In determining which offer” to select, the “the certified IDR entity . . . *shall consider* . . . the qualifying payment

amounts . . . and . . . information on any circumstance described in clause (ii)); *with id.* § 300gg-111(c)(5)(C)(i) (identical); *see TMA*, 2022 WL 542879, at *7 (this text is “unambiguous”).

Section 300gg-112(b)(5)(C) sets forth the “additional circumstances” that the IDR entity “shall consider” when deciding which of the two offers to select in an air ambulance IDR. There are a small number of differences between the “additional circumstances” applicable to air ambulance IDRs and the “additional circumstances” applicable to all other IDRs. However, the crucial statutory language mandating that the IDR entity “shall consider” these additional circumstances is identical for both types of IDRs. *Compare* 42 U.S.C. § 300gg-111(c)(5)(C)(i), *with id.* § 300gg-112(b)(5)(C)(i).

The complete list of statutory “considerations,” including the “additional circumstances,” are as follows:

“Considerations in determination” for <i>non-air ambulance</i> IDRs. 42 U.S.C. § 300gg-111(c)(5)(C).	“Considerations in determination” for <i>air ambulance</i> IDRs. 42 U.S.C. § 300gg-112(b)(5)(C).
“[T]he qualifying payment amounts [QPAs] . . . for the applicable year for items or services that are comparable to the qualified IDR item or service and that are furnished in the same geographic region . . . as such qualified IDR item or service.”	<i>Substantially the same.</i>
“Demonstrations of good faith efforts (or lack of good faith efforts) made by the nonparticipating provider or nonparticipating facility or the plan or issuer to enter into network agreements and, if applicable, contracted rates between the provider or facility, as applicable, and the plan or issuer, as applicable, during the previous 4 plan years.”	<i>Substantially the same.</i>
Any information the IDR entity requests from the parties.	<i>Same.</i>

“Considerations in determination” for <i>non-air ambulance</i> IDRs. 42 U.S.C. § 300gg-111(c)(5)(C).	“Considerations in determination” for <i>air ambulance</i> IDRs. 42 U.S.C. § 300gg-112(b)(5)(C).
Any additional information submitted by a party relating to an offer.	<i>Same.</i>
“The acuity of the individual receiving such item or service or the complexity of furnishing such item or service to such individual.”	<i>Substantially the same.</i>
“The level of training, experience, and quality and outcomes measurements of the provider or facility that furnished such item or service”	“The training, experience, and quality of the medical personnel that furnished such services.” “The quality and outcomes measurements of the provider that furnished such services.”
“The market share held by the nonparticipating provider or facility or that of the plan or issuer in the geographic region in which the item or service was provided.”	The “[a]mbulance vehicle type, including the clinical capability level of such vehicle.”
“The teaching status, case mix, and scope of services of the nonparticipating facility that furnished such item or service.”	The “[p]opulation density of the pick up location (such as urban, suburban, rural, or frontier).”

III. There Is No Relevant Difference Between the Implementing Regulation Regarding *Non-Air Ambulance* IDRs (45 C.F.R. § 149.510) and the Implementing Regulation Regarding *Air Ambulance* IDRs (45 C.F.R. § 149.520)

The full certified administrative record, relevant to this matter, is already before the Court on the *TMA* docket: No. 6:21-CV-425-JDK, at ECF 66.

The NSA directed the Departments, not later than December 27, 2021, to promulgate rules implementing the IDR process. Congress gave *identical directives* in both Section 300gg-111 and Section 300gg-112. *See* 42 U.S.C. § 300gg-111(c)(2)(A); *id.* § 300gg-112(b)(2)(A) (same language, adding only “air ambulance” in a few places).

On September 30, 2021, the Departments publicly released IFR Part II, which contains regulations implementing the IDR process. *Requirements Related to Surprise Billing; Part II*, 86

Fed. Reg. 55,980 (Oct. 7, 2021) (“IFR Part II”). IFR Part II was published in the Federal Register on October 7, 2021, and became effective on that date. *Id.* at 55,980.

As relevant here, IFR Part II requires IDR entities—in *both* kinds of IDRs—to apply the QPA Presumption, that is, a “rebuttable presumption that the QPA is the appropriate payment amount.” *Id.* at 56,060. In other words, the IDR entity—in *both* kinds of IDRs—is to “begin with the presumption that the amount closest to the QPA is the appropriate out-of-network rate.” *Id.* at 55,999. The QPA is to be the “presumptive factor.” *Id.* at 55,996-97. IFR Part II did not distinguish between air ambulance IDRs and other IDRs in any way that is relevant to the QPA Presumption.

The principal provisions of IFR Part II, relating to the IDR Process, are codified in 45 C.F.R. § 149.510.¹ Section 149.510 applies, in full, to any IDR that is *not* an air ambulance IDR.

The very next section—Section 149.520—applies to air ambulance IDRs. This section is much shorter. It simply incorporates, by reference, nearly all of Section 149.510. *See* 45 C.F.R. § 149.520(b)(1).²

Section 149.520(b)(2) directs the IDR entity to consider the different “additional circumstances” that the statute (Section 300gg-112) provides for air ambulance IDRs. Aside from that one difference, air ambulance IDRs are to follow the same procedures that are set forth in Section 149.510, and that apply to all other IDRs. *See* 45 C.F.R. § 149.520(b)(1).

¹ The Departments also codified these regulations under titles 26 and 29 of the Code of Federal Regulations, which concern ERISA and the Internal Revenue Service. These other codifications are the same, in all material respects, as the codifications in the PHS Act regulations that are found in 45 C.F.R. Part 149. For ease of reference, this brief—like *TMA*—cites the PHS Act regulations.

² 45 C.F.R. § 149.520(b)(1) states: “Except as provided in paragraphs (b)(2) and (3) of this section, in determining the out-of-network rate to be paid by group health plans and health insurance issuers offering group or individual health insurance coverage for out-of-network air ambulance services, plans and issuers must comply with the requirements of § 149.510, except that references in § 149.510 to the additional circumstances in § 149.510(c)(4)(iii)(C) shall be understood to refer to paragraph (b)(2) of this section.”

The Departments' QPA Presumption is codified in five parts of 45 C.F.R. § 149.510 and in one sentence of 45 C.F.R. § 149.520, as shown in the chart below. The five parts of Section 149.510 (shown in the first five rows) were expressly vacated by *TMA*. The one sentence from Section 149.520 (shown in the sixth and final row of the chart) was not expressly vacated by *TMA*, but is word-for-word identical to a provision in Section 149.510 that was vacated (these identical provisions are indicated by highlighting):

Regulatory Text (bold language contains the QPA Presumption)	Citation
<p>“(viii) Material difference means a substantial likelihood that a reasonable person with the training and qualifications of a certified IDR entity making a payment determination would consider the submitted information significant in determining the out-of-network rate and would view the information as showing that the qualifying payment amount is not the appropriate out-of-network rate.”</p>	<p>45 C.F.R. § 149.510(a)(2)(viii)</p>
<p>ii) Payment determination and notification. Not later than 30 business days after the selection of the certified IDR entity, the certified IDR entity must:</p> <p>(A) Select as the out-of-network rate for the qualified IDR item or service one of the offers submitted under paragraph (c)(4)(i) of this section, taking into account the considerations specified in paragraph (c)(4)(iii) of this section (as applied to the information provided by the parties pursuant to paragraph (c)(4)(i) of this section). The certified IDR entity must select the offer closest to the qualifying payment amount unless the certified IDR entity determines that credible information submitted by either party under paragraph (c)(4)(i) clearly demonstrates that the qualifying payment amount is materially different from the appropriate out-of-network rate, or if the offers are equally distant from the qualifying payment amount but in opposing directions.</p>	<p>45 C.F.R. § 149.510(c)(4)(ii)(A)</p>

Regulatory Text (bold language contains the QPA Presumption)	Citation
<p>(iii) Considerations in determination. In determining which offer to select, the certified IDR entity must consider:</p> <p>...</p> <p>(C) Additional information submitted by a party, provided the information is credible and relates to the circumstances described in paragraphs (c)(4)(iii)(C)(1) through (5) of this section, with respect to a qualified IDR item or service of a nonparticipating provider, facility, group health plan, or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.</p>	<p>45 C.F.R. § 149.510(c)(4)(iii)(C)</p>
<p>(iv) Examples. The rules of paragraph (c)(4)(iii) of this section are illustrated by the following examples: ... [four examples illustrating the QPA Presumption].</p>	<p>45 C.F.R. § 149.510(c)(4)(iv)</p>
<p>(B) If the certified IDR entity does not choose the offer closest to the qualifying payment amount, the certified IDR entity's written decision must include an explanation of the credible information that the certified IDR entity determined demonstrated that the qualifying payment amount was materially different from the appropriate out-of-network rate, based on the considerations allowed under paragraph (c)(4)(iii)(B) through (D) of this section, with respect to the qualified IDR item or service.</p>	<p>45 C.F.R. § 149.510(c)(4)(vi)(B)</p>
<p>(b) Determination of out-of-network rates to be paid by health plans and health insurance issuers; independent dispute resolution process—</p> <p>....</p> <p>(2) Additional information. Additional information submitted by a party, provided the information is credible, relates to the circumstances described in paragraphs (b)(2)(i) through (vi) of this section, with respect to a qualified IDR service of a nonparticipating provider of air ambulance services or health insurance issuer of group or individual health insurance coverage that is the subject of a payment determination. This information must also clearly demonstrate that the qualifying payment amount is materially different from the appropriate out-of-network rate.</p>	<p>45 C.F.R. § 149.520(b)(2)</p>

IV. The Departments Continue to Require the QPA Presumption in Air Ambulance IDRs

On April 12, 2022, the Departments issued “guidance” to IDR entities that requires the IDR Entities to continue applying the QPA Presumption in air ambulance IDRs, as follows:

6.4.1. When and How to Apply the QPA for Disputes Involving Air Ambulance Qualified IDR Services

For **air ambulance qualified IDR services**, in determining which payment offer to select, the certified IDR entity should consider **credible information** submitted by either party in relation to the offer to the extent that the information **clearly demonstrates** that the QPA is **materially different** from the appropriate OON rate for the qualified air ambulance service, based on the additional circumstances described in Section 6.4.2.

In cases where credible information clearly demonstrates that the QPA is materially different from the appropriate OON rate, or when the offers are equally distant from the QPA but in opposing directions, the certified IDR entity must select the offer that the certified IDR entity determines best represents the value of the air ambulance qualified IDR items or services, which could be either offer submitted.

Federal Independent Dispute Resolution (IDR) Process Guidance for Certified IDR Entities, at 22 (Apr. 12, 2022), *available at* <https://www.cms.gov/sites/default/files/2022-04/Revised-IDR-Process-Guidance-Certified-IDREs.pdf>. This Guidance is attached as Exhibit 1 hereto, and the just-quoted language appears on page 22.

The Guidance states that the QPA Presumption should *not* be applied in non-air-ambulance IDRs. Specifically, Section 6.3 of the Guidance—a section entitled “Payment Determinations Involving Non-Air Ambulance Qualified IDR Items and Services”—states that IDR entities must consider *all* credible information submitted relating to the relevant “additional circumstances.” Ex. 1, at 19-20. This Section does *not* contain the limitation, quoted above in Section 6.4.1, that additional information should only be considered “to the extent that the information **clearly demonstrates** that the QPA is **materially different** from the appropriate” rate. *See id.*

The Guidance does not provide any explanation for this difference between air ambulance IDRs and all other IDRs.

V. Undisputed Material Facts Relevant to Plaintiff's Standing

The first Gaines Declaration, re-attached hereto as Exhibit 2, establishes that LifeNet is regulated by the NSA and its implementing regulations. Specifically, LifeNet is a “nonparticipating provider” (i.e., out-of-network provider) of air ambulance services for emergency patients with commercial health plans or commercial health insurance. *See* Ex. 2 (Gaines Decl.), ¶ 3. Indeed, LifeNet has *already provided* air ambulance transports, in 2022, that may soon be subjected to the IDR process. *Id.* ¶ 4. The QPA Presumption will result in lower dollar valuations for LifeNet’s services in these IDRs than would have been awarded without the presumption. *Id.* ¶ 9. The QPA Presumption will “drive out-of-network reimbursement rates” for LifeNet’s services “to the QPA as a benchmark.” *Id.* ¶ 10. This systematic reduction of out-of-network reimbursement rates, to the QPA amount, is the *intended effect* of the QPA Presumption—as Defendants acknowledged in *TMA*. *See* Defendants’ Cross-Motion for Summary Judgment, *TMA*, No. 6:21-CV-425-JDK, ECF 62, at 10–11, 22, 32, 37 (filed Jan. 10, 2022).

In response to Plaintiff’s motion seeking expedited briefing, Defendants asserted that they intend to challenge Plaintiff’s standing based on the fact that Plaintiff is directly compensated for its emergency air transports by non-party Air Methods Corporation (“Air Methods”), pursuant to a contract between those two companies. This contract sets an agreed amount of compensation for LifeNet’s emergency air transport services, which amount is to be paid to LifeNet by Air Methods. According to the contract, Air Methods is responsible for collecting reimbursement from other payors (e.g., patients, health plans, health insurers) for LifeNet’s services. But Air Methods owes the agreed amount to LifeNet, for a given transport, even if Air Methods is unsuccessful at collecting reimbursement for that transport from other payors. The contract entered into force in October 2021. Ex. 2 (Gaines Decl.), ¶ 5. It is of “limited duration.” *Id.*

The second Gaines declaration, attached hereto as Exhibit 3, provides more information about this contract. Although the contract entered into force in October 2021, it was *executed* more than a month earlier, on August 24, 2021—well before IFR Part II, containing the QPA Presumption, was published. Ex. 3 (Second Gaines Decl.), ¶ 2. The contract can be terminated early, by Air Methods, in the event of a “decline in revenue.” *Id.* ¶ 3. Specifically, the contract states that if Air Methods’ reimbursement from other payors “drops to a financially unviable situation that is beyond the reasonable expectations” of the parties on August 24, 2021, when they signed the contract, then Air Methods “may terminate all or part of” the contract. *Id.*

The QPA Presumption—and the decline in reimbursement rates that it will cause—was not within “the reasonable expectations” of LifeNet and Air Methods on August 24, 2021, since at that point in time the Defendants had not yet published their contrary-to-statute QPA Presumption. *See id.* ¶ 4. There is a “significant risk” that the decline in revenue, caused by the QPA Presumption, will create a “financially unviable situation.” *Id.* There is a “significant risk” that LifeNet’s contractual rights to compensation, from Air Methods, will be terminated or reduced because of the decline in revenues caused by the QPA Presumption. *Id.*

ARGUMENT

I. The QPA Presumption Conflicts with the Statutory Text of the NSA

The NSA “unambiguously establishes the framework for deciding payment disputes” between air ambulance providers and commercial payors. *TMA*, 2022 WL 542879, at *7. The QPA Presumption, as enacted in Section 149.520(b)(2), “conflicts with the statutory text.” *Id.*

Section 300gg-112, like Section 300gg-111, is “unambiguous.” *Id.* Section 300gg-112 provides that in an air ambulance IDR, the IDR entity “shall consider . . . the qualifying payment amounts . . . and . . . information on any circumstance described in clause (ii).” 42 U.S.C. § 300gg-

112(b)(5)(C). This Court, in *TMA*, found identical language in Section 300gg-111 to be “unambiguous.” *TMA*, 2022 WL 542879, at *7 (quoting Section 300gg-111(c)(5)(C)(i)).

A few of the “additional circumstances” to be considered by the IDR entity in an air ambulance IDR differ from the “additional circumstances” to be considered in a *non*-air-ambulance IDR. However, the instruction to the IDR entity—that it “shall” consider these circumstances—is the same for all IDRs and identical in both statutory provisions.

“Because the word ‘shall’ usually connotes a requirement, the Act plainly requires arbitrators to consider all the specified information in determining which offer to select.” *TMA*, 2022 WL 542879, at *7 (quoting *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016)).

Nothing in the Act instructs arbitrators, in an air ambulance IDR, to “weigh any one factor or circumstance more heavily than the others.” *TMA*, 2022 WL 542879, at *8. That “lack of text” is “more telling” than the text itself. *Id.* (quoting *Gulf Fishermens Ass’n v. Nat’l Marine Fisheries Serv.*, 968 F.3d 454, 460 (5th Cir. 2020)). Congress knows how to create a rebuttable assumption when it wishes to do so. *See id.* (citing examples of other provisions of the U.S. Code that create rebuttable presumptions). Congress did not do so here.

“Because Congress spoke clearly on the issue relevant here, the Departments’ interpretation of the statute is owed no *Chevron* deference.” *Id.*

“Because the Rule rewrites clear statutory terms, it must be held unlawful and set aside on this basis alone.” *Id.* at *9 (cleaned up) (citing *Util. Air Regul. Grp. v. E.P.A.*, 573 U.S. 302, 328 (2014) and 5 U.S.C. § 706(2)(A)).

II. The QPA Presumption Should Be Set Aside Because the Departments Failed to Provide for Public Notice and Comment

The APA requires federal agencies to publish a “notice of proposed rule making” and to “give interested persons an opportunity to participate ... through submission of written data, views, or arguments.” 5 U.S.C. § 553(b), (c). The purpose of the “notice-and-comment” requirement is to “assure fairness and mature consideration of rules having a substantial impact on those regulated” and for the agency to “disclose its thinking on matters that will affect regulated parties.” *TMA*, 2022 WL 542879, at *10 (quoting *United States v. Johnson*, 632 F.3d 912, 931 (5th Cir. 2011)). Unless an agency can show an exception to the APA’s notice-and-comment requirement, the regulation is “contrary to law” and must be “set aside.” *Id.* (quoting 5 U.S.C. § 706(2)(A)).

A. There Is No Exception to Notice-and-Comment for Regulations Concerning Air Ambulance IDRs

The APA allows a statute to modify or supersede the APA’s procedural requirements “to the extent [the statute] does so expressly.” 5 U.S.C. § 559. The NSA did not “expressly” provide for any exception to the APA’s notice-and-comment requirement. This Court already conducted this analysis with respect to Section 300gg-92, which authorizes the Departments to “promulgate any interim final rules as the Secretary determinates are appropriate.” *See TMA*, 2022 WL 542879, at *10. The *TMA* analysis also controls the outcome here. Section 300gg-92 applies to “this subchapter,” which includes both Section 300gg-111 and Section 300gg-112 and thus applies to all types of IDRs.

B. There Was No “Good Cause” For Not Providing Notice and Comment

In *TMA*, the Departments offered various reasons why they contended that “good cause” existed for not allowing notice-and-comment. *See TMA*, 2022 WL 542879, at *11-*12 (rejecting the Departments’ “good cause” contentions). Since the sole provision relevant here—the sixth

provision, contained in Section 149.520(b)(2)—was enacted together with the other five provisions in IFR Part II, the “good cause” analysis in *TMA* applies in full to this case.

The Departments cannot show that the failure to provide for notice-and-comment was “harmless.” *TMA*, 2022 WL 542879, at *13-*14. “If the Departments had provided notice and comment,” then Plaintiff LifeNet, and other air ambulance providers, and other emergency medical providers affected by the QPA Presumption, “could have submitted the specific reasons and authorities for why they believed the Rule [i.e., the QPA Presumption] is inconsistent with the Act, how the Rule would impact them as providers, and how the Rule could be drafted to track the statutory text more closely. On the record before the Court, the Departments cannot demonstrate that they considered and fully addressed these issues.” *TMA*, 2022 WL 542879, at *13.

III. The Departments’ Application of the QPA Presumption *Solely* In Air Ambulance IDRs, And *Not* In Other IDRs, Conflicts with the Statute and Is Arbitrary and Capricious

The two bases for vacating the final sentence of Section 149.520(b)(2), which were described above and applied in *TMA*, are each a complete and independent basis for granting this relief.

Solely as an alternative, however, this sentence should also be vacated for an additional reason, namely: the current differential treatment of air ambulance providers is arbitrary and capricious. 5 U.S.C. § 706(2)(A).

As the attached April 12 “guidance” indicates, the Departments are currently applying the QPA Presumption solely in air ambulance IDRs, and *not* in any other kinds of IDRs. *Supra*, at 10 (describing Exhibit 1). This “guidance” provides no explanation of why the Departments believe it is appropriate for air ambulance IDRs to be treated any differently from all other IDRs for purposes of the QPA Presumption. The “guidance” is mere *fiat*—it asserts, without any reasoned

basis, that the QPA Presumption must remain in effect in air ambulance IDRs. There is no statutory or rational basis for this discriminatory treatment.

The statute does not provide for any different use of the QPA, in air ambulance IDRs, from all other IDRs. On the contrary, the relevant statutory text regarding the use of the QPA is identical in both Section 300gg-111 and Section 300gg-112: the IDR entity “*shall consider . . . the qualifying payment amounts . . . and . . . information on any circumstance described in clause (ii).*” 42 U.S.C. § 300gg-112(b)(5)(C) (emphasis added); *id.* § 300gg-111(c)(5)(C)(i). Because the statutory text is so clear—and is so clearly *the same*—the Departments should not receive any *Chevron* deference for their current decision to apply the QPA Presumption *solely* in air ambulance IDRs and not in any other IDRs.

The Departments’ formal rulemaking (IFR Part II) provides no explanation or justification for according the QPA any greater weight, in air ambulance IDRs, than in other IDRs. On the contrary, that rulemaking described the QPA Presumption as applying equally to all IDRs. *See generally* IFR Part II. Because the newly announced differential treatment, for air ambulance IDRs, is not enacted in any formal rulemaking, this differential treatment is not entitled to deference under the *Chevron* doctrine. *See Smiley v. Citibank (S. Dakota), N.A.*, 517 U.S. 735, 740–41 (1996) (explaining that *Chevron* deference is appropriately applied to “a full-dress regulation” but *not* to “agency litigating positions that are wholly unsupported by regulations, rulings, or administrative practice”).

The April 12 “guidance” (and the Departments’ forthcoming opposition brief to this Motion) are not entitled to deference under the *Auer* doctrine, since the differential treatment of air ambulance IDRs is contrary to the formal rulemaking of the Departments that was published in IFR Part II. That rulemaking treated all IDRs the same for purposes of the QPA. *Auer* deference

does not apply to an agency’s litigation position that is wholly at odds with the agency’s published regulation. *See Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155-156 (2012) (*Auer* deference, to an agency’s interpretation of “its own ambiguous regulation,” is “undoubtedly inappropriate” where the interpretation is plainly erroneous or inconsistent with the promulgated regulation or is “nothing more than a *post hoc* rationalization advanced by an agency seeking to defend past agency action against attack”) (cleaned up)).

The Department’s recent decision to treat air ambulance IDRs differently, for purposes of the QPA Presumption, is arbitrary and capricious for at least the following four reasons: (1) the differential treatment has no statutory basis, *see Judulang v. Holder*, 565 U.S. 42, 55 (2011); (2) there is no “rational connection” between a provider’s status (as an air ambulance provider or as some other kind of provider) and the applicability of the QPA Presumption, *see Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); (3) the differential treatment of air ambulance providers is illogical, *see Venetian Casino Resort, L.L.C. v. EEOC*, 530 F.3d 925, 934 (D.C. Cir. 2008); and (4) the Departments failed to provide any coherent explanation for why they are now treating air ambulance IDRs differently from all other IDRs, *see Fox v. Clinton*, 684 F.3d 67, 80 (D.C. Cir. 2012).

IV. LifeNet Has Standing

A. Article III Standing

1. LifeNet Is An “Object Of” of the Challenged Regulations

Standing is generally “self-evident” where, as here, the challenge is brought by a regulated party. *Am. Petroleum Inst. v. Johnson*, 541 F. Supp. 2d 165, 176 (D.D.C. 2008) (“[S]tanding is usually self-evident when the plaintiff is a regulated party.”); *see also Markle Interests, LLC v. U.S. Fish & Wildlife Serv.*, 40 F. Supp. 3d 744, 756 (E.D. La. 2014). That is because when a party is an “object of” government action, there is “ordinarily little question that the [government]

action” concretely affects the party, causing an injury in fact that supports standing. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992). So the law, in this Circuit as elsewhere, is that the “object of a government” rule “ordinarily has standing to challenge” that rule. *Duarte v. City of Lewisville*, 759 F.3d 514, 518 (5th Cir. 2014).

The First Gaines Declaration, re-attached hereto as Exhibit 2, establishes that Plaintiff LifeNet is a regulated party who is an “object of” the challenged regulations. LifeNet is a “nonparticipating provider” (i.e., out-of-network provider) of air ambulance services for which compensation is governed by the NSA and its implementing regulations. *See* Ex. 2 (First Gaines Decl.), ¶ 3. Indeed, LifeNet has *already provided* air ambulance transports, in 2022, that may soon be subjected to the IDR process. *Id.* ¶ 4. LifeNet’s services will be analyzed by the IDR entities, and LifeNet’s services will be valued by the IDR entities’ determinations, which will assign a dollar value to LifeNet’s services after considering all the other “additional circumstances” that pertain to LifeNet and to LifeNet’s specific services at issue. *See* 42 U.S.C. § 300gg-112(b)(5)(C) (IDR entity “shall consider” LifeNet’s personnel’s “training, experience, and quality” and LifeNet’s “quality and outcomes measurements”).

LifeNet remains a regulated party, with standing to challenge these regulations, even though LifeNet’s compensation is (for the moment at least) paid by non-party Air Methods pursuant to the contract between those two companies. *Supra*, at 10-11. Regardless of that contractual arrangement, LifeNet remains an “object of” the challenged rule because it is LifeNet’s services that are valued in the IDR proceeding. *See, e.g., Meland v. Weber*, 2 F.4th 838, 845 (9th Cir. 2021) (shareholder had Article III standing to challenge state law mandating female representation on corporation’s board of directors because shareholder was also “one of the objects” of the law); *Owner-Operator Indep. Drivers Ass’n, Inc. v. Fed. Motor Carrier Safety*

Admin., 656 F.3d 580, 585–86 (7th Cir. 2011) (individual truckers had standing because they were “objects” of rule requiring on-board recording devices, even though the rule directly regulated only the truckers’ *employers*, the “motor carrier” companies).

Because LifeNet and LifeNet’s services are analyzed and valued in the IDR proceedings, LifeNet suffers three distinct kinds of “injury in fact” as a result of the challenged QPA Presumption, even though LifeNet’s compensation for these services is (for the moment) paid by Air Methods pursuant to the contract.

2. Procedural Injury to LifeNet

A plaintiff can show a cognizable injury-in-fact if he or she has “been deprived of ‘a procedural right to protect [his] concrete interests.’” *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019); *see also Lujan*, 504 U.S. at 573 n.8. The plaintiff “need not prove that following proper procedure will necessarily create different outcomes,” but rather “must merely show a reasonable claim of minimal impact.” *TMA*, 2022 WL 542879, at *4 (cleaned up).

There is procedural injury here, just as there was in *TMA*. In the NSA, Congress carefully designed an IDR procedure—one in which an independent arbitrator would resolve reimbursement disputes based on all relevant factors—to protect the economic interests of air ambulance providers like LifeNet. The QPA Presumption strips away that protection by replacing Congress’s balanced scheme with the unlawful presumption that IDR entities must select the offer closest to the QPA. LifeNet has standing to vindicate this procedural right because LifeNet provides air ambulance transport services that are subject to the IDR Process, Ex. 2 (Gaines First Decl.), ¶ 3, and because “in many and perhaps all cases” the offer submitted to the IDR entity, for LifeNet’s services, will “be above the QPA.” *Id.* ¶ 7.

3. Economic Injury to LifeNet

LifeNet is in a similar economic position as Dr. Adam Corley, the individual plaintiff in *TMA*. Dr. Corley did not himself seek reimbursement from the health plans and insurers; nor did he personally participate in the IDR process. Instead, Dr. Corley was paid an hourly salary by non-party Precision Emergency Physicians, PLLC, which company was responsible for collecting reimbursement from the plans and insurers and, in the event of a dispute, was responsible for engaging in the IDR process. *TMA*, Corley Supp. Decl., Dkt. 98-4, ¶ 3. Dr. Corley nevertheless had standing because, as his declaration attested, the QPA Presumption will “result in lower reimbursement rates for my services ... and, correspondingly, will cause my hourly compensation ... to decrease.” *Id.* ¶ 8. The Court correctly held that this economic injury is “a quintessential injury upon which to base standing.” *TMA*, 2022 WL 542879, at *5 (citing Dr. Corley’s Supplemental Declaration, among others).

In similar fashion, LifeNet is directly reimbursed for its services by Air Methods. Nevertheless, the QPA Presumption “will drive out-of-network reimbursement rates to the QPA as a benchmark. That in turn will cause LifeNet’s compensation to decrease significantly.” Ex. 2 (Gaines Decl.), ¶ 11.

This economic injury may not occur right away. For the moment, at least, Air Methods is honoring its contractual obligation to pay LifeNet the agreed-upon amount for LifeNet’s services. But there is a “significant risk” that this contract will be terminated (and the payments to LifeNet reduced or ceased entirely) if QPA Presumption’s systematic reduction of IDR payments to the QPA benchmark makes the agreed-upon contractual amounts “financially unviable.” Ex. 3 (Second Gaines Decl.), ¶ 4. A “substantial risk that the harm will occur” in the future qualifies as an injury-in-fact for purposes of Article III. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (substantial risk of future enforcement conferred standing). A substantial risk of future

economic harm “immediately and directly affects the borrowing power, financial strength, and fiscal planning” of the party that must plan for that future economic harm. *Clinton v. City of New York*, 524 U.S. 417, 431 (1998). In *City of New York*, the Court held that New York City had standing to challenge the constitutionality of President Clinton’s line-item veto, of an item that had eliminated a potential “contingent liability” of the city. *Id.* at 423. The city had standing even though its potential future “liability” would only come due if the Department of Health & Human Services denied a “waiver request” that had been submitted to it. *See id.* at 422 (“Because HHS had not taken any action on the waiver requests, New York turned to Congress for relief.”); *id.* at 426 (“If HHS ultimately denies the State’s waiver requests, New York law will automatically require [the city corporation] to make retroactive tax payments to the State.”); *see also Ass’n of Data Processing Serv. Organizations, Inc. v. Camp*, 397 U.S. 150, 152 (1970) (plaintiff had Article III standing to challenge ruling by Comptroller of the Currency, which exposed plaintiff to increased competition, because the increased competition “might entail some future loss of profits” to plaintiff).

4. Injury to LifeNet from Lower Dollar Valuations, by IDR Entities, for LifeNet’s Services

In addition to the procedural and economic injuries-in-fact already discussed, LifeNet also suffers an immediate injury-in-fact from IDR entities low dollar valuations of LifeNet’s services. *See* Gaines First Decl. ¶ 10. Low dollar valuations, by these federally certified arbitrators, cause immediate concrete harm regardless of the fact that LifeNet may be paid some different dollar amount, for the specific services in question, as a result of LifeNet’s contract with Air Methods.

To be sure, the harm from a low dollar valuation is intangible. But a harm does not need to be “tangible” to provide Article III standing. *Cranor v. 5 Star Nutrition, L.L.C.*, 998 F.3d 686, 689-90 (5th Cir. 2021). In *Cranor*, the Fifth Circuit held that the “nuisance” caused by receiving a

“single unwelcome text message” was sufficiently “concrete” to constitute an injury-in-fact. *Id.* Similarly, the inaccurate reporting of credit information—e.g., age and marital status—has been held to be a sufficiently “concrete” injury to confer standing, even absent any reputational harm or monetary loss. *Robins v. Spokeo, Inc.*, 867 F.3d 1108, 1115 (9th Cir. 2017) (on remand from Supreme Court), *cert. denied*, 138 S. Ct. 931 (2018).

A low dollar valuation, determined in an IDR proceeding, is an immediate concrete harm to LifeNet despite being “intangible.” The NSA has drastically restricted the relevant market for LifeNet’s emergency air transport services. By their very nature, emergency transport services are unplanned, unscheduled, and payment for them cannot be negotiated with the patient in advance. The NSA forbids LifeNet from seeking compensation from the emergency patient after the transport has occurred, for any amount in excess of the patient’s “cost sharing.” *See* 42 U.S.C. § 300gg-135. Thus, the market for LifeNet’s emergency transport services is now limited, by the NSA, to reimbursement from the commercial health plans and insurers that cover LifeNet’s emergency patients. And the valuation that matters most, in that market, is the valuation determined by the IDR entities. Commercial health plans and insurers are sophisticated economic actors that will not agree to pay LifeNet any more than what they believe LifeNet can obtain through the IDR process. The imminent IDR determinations will (as a result of the QPA Presumption) assign lower-than-appropriate dollar values to LifeNet’s services. Those lower dollar valuations will be reported immediately to each counter-party (i.e., each payor). Therefore, the dollar value of LifeNet’s services, in this “critically important market,” will be directly and (and negatively) affected by the QPA Presumption. Ex. 2 (Gaines Decl.), ¶ 10.

These lower dollar valuations, resulting from imminent IDR determinations, are far more consequential than other intangible harms that have been held to be sufficiently “concrete”

purposes of Article III. *See Cranor*, 998 F.3d at 689 (a “single unwelcome text message” was a sufficiently “concrete” injury-in-fact); *Robins*, 867 F.3d at 1115 (website’s inaccurate reporting of plaintiff’s age, marital status, and similar information was a sufficiently “concrete” injury-in-fact).

Moreover, lower-than-appropriate dollar valuations, for LifeNet’s services, are analogous to injuries recognized at common law. *See Cranor*, 998 F.3d at 691 (finding Article III standing, in part, because a claim based on a “single unwelcome text message” bore a close relationship to a claim for “public nuisance” as recognized at common law). This inquiry “is focused on *types of harms* protected at common law, not the precise point at which those harms become actionable” under common law. *Id.* at 693 (emphasis added) (quoting *Krakauer v. Dish Network, L.L.C.*, 925 F.3d 643, 654 (4th Cir. 2019)). Lower-than-appropriate dollar valuations of LifeNet’s services bear a close relationship to the kinds of injuries recognized at common law for untrue and disparaging statements about another’s “chattels or intangible things.” Restatement (First) of Torts § 624 (1938); *see also* Restatement (Second) of Torts §§ 623A-629 (1977).

B. LifeNet Has “Prudential” Standing

LifeNet has “prudential” or “statutory” standing because, as a “nonparticipating provider” of covered out-of-network services under the NSA, LifeNet is within the “zone of interests” of the NSA’s IDR provisions. *See, e.g., Match-E-Be-Nash-She-Wish Band of Pottawatomí Indians v. Patchak*, 567 U.S. 209, 224–25 (2012).

CONCLUSION

For the foregoing reasons, Plaintiff LifeNet respectfully requests an order vacating the final sentence of 45 C.F.R. § 149.520(b)(2), the final sentence of 26 C.F.R. § 54.9817-2T(b)(2), and the final sentence of 29 C.F.R. § 2590.717-2(b)(2).

Dated: May 18, 2022

BY:

/s/ Steven M. Shepard
Steven M. Shepard (*pro hac vice*)
Stephen Shackelford, Jr. (EDTX Bar No.
24062998)
Max I. Straus (*pro hac vice*)
James Craig Smyser (*pro hac vice*)
SUSMAN GODFREY LLP
1301 Ave. of the Americas, Fl. 32
New York, NY 10019
sshackelford@susmangodfrey.com
212-336-8340

Counsel to Plaintiff LifeNet, Inc.

CERTIFICATE OF SERVICE

I certify that I caused the foregoing document to be filed on the CM/ECF system on May 18, 2022, which will effect service on all counsel of record.

Steven M. Shepard
Steven M. Shepard